Case 4:05-cr-00346

Document 1

Filed in TXSD on 08/24/2005

Public and unofficial staff access to this instrument are

AUG 2 4 2005

IN THE UNITED SO HIS THE COURT OF THE CO FOR THE SOUTHERN DISTRICT OF TEXAS

HOUSTON DIVISION

MICHAEL N. MILBY, CLERK OF COURT

UNITED STATES OF AMERICA

v.

Plaintiff,

§ § § CRIMINAL NO.

H-05-346

18 U.S.C. § 371

21 U.S.C. § 331(a)

21 U.S.C. § 331(i)

21 U.S.C. § 333(b)(1)(A) JAMES GEORGE

Defendant.

INDICTMENT

THE GRAND JURY CHARGES:

COUNT ONE (Conspiracy – 18 U.S.C. § 371)

A. INTRODUCTION

At all times material to this indictment:

- The United States Food and Drug Administration (FDA) is the agency of the United 1. States charged with the responsibility of protecting the health and safety of the American public by ensuring, among other things, that drugs sold for administration to humans bear labeling containing true and accurate information. The FDA's responsibilities include regulating the labeling and distributing of prescription drugs shipped or received in interstate commerce.
- Under the Food Drug and Cosmetic Act, the definition of a "drug" includes articles which (1) are intended for use in the diagnoses, cure, mitigation, treatment or prevention of disease in man, and (2) are intended to affect the structure or function of the body of man. Due to the toxicity and other potential harmful effect, certain drugs are not considered safe for use except for use under the supervision of a practitioner licensed by law to administer such drugs.

These drugs are known as prescription drugs.

- 3. Viagra was a prescription drug product that had been approved by the FDA for distribution within the United States.
- 4. Pfizer Pharmaceuticals (Pfizer) had the exclusive right to manufacture Viagra for distribution within the United States.
- 5. The name "Viagra" was a trademark owned by Pfizer and is registered in the principal registry in the United States Patent and Trademark Office.
- 6. Cialis was a prescription drug product that had been approved by the FDA for distribution within the United States.
- 7. Eli Lilly Corporation (Eli Lilly) had the exclusive right to manufacture Cialis for distribution within the United States.
- 8. The name "Cialis" was a trademark owned by Eli Lilly and is registered in the principal registry in the United States Patent and Trademark Office.
- 9. The Food Drug and Cosmetic Act also regulates the importation, delivery, distribution and receipt of prescription drugs in interstate commerce. Under the Act, a prescription drug is deemed misbranded if its labeling is false or misleading in any particular manner. A prescription drug is also deemed to be counterfeit if it bears a trademark without the authorization of the registrant of the trademark.
- 10. James George, defendant herein, was a pharmacist licensed by the State of Texas to receive, dispense and sell pharmaceutical drugs. James George was the owner and operator of LIFEWAY PHARMACY, 1313 Holland Ave. Suite D, Jacinto City, Texas 77029.

B. THE CONSPIRACY

11. Beginning in or about August, 2004 and continuing thereafter to on or about December 13, 2004, in the Houston Division of the Southern District of Texas and elsewhere, defendant,

JAMES GEORGE

did knowingly, intentionally, and willfully combine, conspire and confederate and agree with other persons unknown to the grand jury to commit certain offenses against the United States, namely:

- a. To violate the Food, Drug and Cosmetic Act, namely, to knowingly import

 Prescription Drugs, specifically Viagra and Cialis, without the authorization of the

 manufacturer of said drugs, in violation of Title 21, United States Code, Section

 333(b)(1)(A);
- b. To violate the Food, Drug and Cosmetic Act, namely, with the intent to defraud and mislead, cause the introduction and delivery for introduction of prescription drugs into interstate commerce that are misbranded, in violation of Title 21, United States Code, Section 331(a) and 333(a)(2).
- c. To violate the Food, Drug and Cosmetic Act, namely, with the intent to defraud and mislead, cause the counterfeiting of trademarks Viagra and Cialis in violation of Title 21, United States Code, Section 331(i), 333(a)(2)

Page 4 of 8

C. OBJECT OF THE CONSPIRACY

12. It was the object of the conspiracy for the defendant and others to unlawfully enrich themselves by importing pharmaceutical drug products that bore the trademarks Viagra and Cialis, without the authorization of manufacturer of said drugs, and thereafter resell the drugs to the public.

D. MANNER AND MEANS

The manner and means of the conspiracy included, but were not limited to the following:

- 13. Defendant JAMES GEORGE would and did contact individuals residing in the Republic of China regarding the manufacture and importation of counterfeit Cialis and Viagra into the United States.
- 14. Defendant JAMES GEORGE would and did place an order with individuals residing in the Republic of China for counterfeit pharmaceutical drugs in tablet form purported to contain 100mg of Viagra and 20mg of Cialis.
- 15. Defendant JAMES GEORGE would and did cause individuals residing in the Republic of China to place the counterfeit Viagra and Cialis in interstate commerce by delivering the drugs to a common carrier for airfreight shipment to himself at 16422 Concord Falls Lane, Sugarland Texas 77478.
- 16. Defendant JAMES GEORGE would and did cause individuals to ship counterfeit pharmaceuticals from China to United States. The pharmaceuticals were counterfeit in that they were falsely represented to be Pfizer brand Viagra tablets and Eli Lilly brand Cialis tablets. The counterfeit tablets bore the same mark, shape and appearance as the genuine Viagra and Cialis tablets.
 - 17. Defendant JAMES GEORGE would and did cause individuals to ship misbranded

pharmaceuticals from China to the United States. The pharmaceuticals were misbranded in that

- a. The labeling affixed to the bottles falsely represented that the bottles contained genuine Viagra and Cialis pharmaceutical products; and
 - b. The tablets were manufactured and dispensed from a non-FDA approved facility.

OVERT ACTS

- 18. In furtherance of the conspiracy and to effect the objects thereof, the following Overt Acts, among others, were committed in the Southern District of Texas,
- (1) On or about October 9, 2004, defendant JAMES GEORGE, using a computer contacted a coconspirator residing in the Republic of China regarding the purchase of counterfeit Viagra and Cialis pharmaceutical drugs.
- (2) On or about October 27, 2004, defendant JAMES GEORGE, using a computer, contacted a coconspirator residing in the Republic of China and placed an order for counterfeit pharmaceutical drugs, specifically 4500 tablets of Viagra 100mg and 1000 tablets of Cialis 20mg.
- (3) On or about October 29, 2004, defendant JAMES GEORGE wired transferred approximately \$1600 to a coconspirator residing in the Republic of China as payment for the counterfeit Viagra and Cialis pharmaceutical drugs.
- (4) On or about October 30, 2004, defendant JAMES GEORGE caused a shipment containing counterfeit Viagra and Cialis pharmaceutical drugs to be sent by airfreight from China to Dallas Fort Worth Airport in Forth Worth, Texas with eventual delivery to himself at 16422 Concord Falls Lane, Sugarland, Texas 77478.
- (5) On or about October 30, 2004, defendant JAMES GEORGE caused a shipment containing bottles of counterfeit Viagra and Cialis to be labeled in manner that falsely

represented the bottles to contain the genuine Viagra and Cialis pharmaceutical drugs.

- (5) On or about December 8, 2004, defendant JAMES GEORGE contacted an employee of Menlo Worldwide Delivery, the consignee for the shipment regarding the delivery of the counterfeit and misbranded pharmaceutical drugs. The defendant provided cellular telephone number (832) 275-8411 as a contact number.
- (6) On or about December 13, 2004, defendant JAMES GEORGE met with undercover FDA agent posing as an employee of Menlo Worldwide Delivery and received the counterfeit Viagra and Cialis pharmaceutical products.

In violation of Title 18, United States Code, Section 371.

COUNT TWO (Misbranded Drugs)

1. On or about October 30, 2004, in the Houston Division of the Southern District of Texas, the defendant,

JAMES GEORGE

with the intent to defraud and mislead, caused the introduction and delivery for introduction into interstate commerce drugs that were misbranded, namely that a shipment containing bottles of counterfeit Viagra and Cialis were labeled in a manner to falsely represent that the bottles contained the genuine Viagra and Cialis pharmaceutical drugs.

In violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

COUNT THREE (Counterfeit Drugs)

1. On or about October 30, 2004, in the Houston Division of the Southern District of Texas, the defendant,

JAMES GEORGE

with the intent to defraud and mislead, caused a drug to be labeled with the trademark Viagra without the authorization and permission of Pfizer Pharmaceuticals, the registered holder of said trademark..

In violation of Title 21 United States Code, Sections 331(i) and 333(a)(2).

COUNT FOUR (Counterfeit Drugs)

1. On or about October 30, 2004, in the Houston Division of the Southern District of Texas, the defendant,

JAMES GEORGE

with the intent to defraud and mislead, caused a drug to be labeled with the trademark Cialis without the authorization and permission of Eli Lilly Corporation, the registered holder of said trademark..

In violation of Title 21 United States Code, Sections 331(i) and 333(a)(2).

COUNT FIVE (Importation of Drugs)

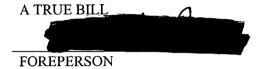
1. On or about October 30, 2004, in the Houston Division of the Southern District of

Texas, the defendant,

JAMES GEORGE

aided and abetted by others unknown to the Grand Jury, did knowingly and intentionally import pharmaceutical drugs bearing the trademarks Viagra and Cialis from China into the United States without the authorization of the registered holder of such trademarks.

In violation of Title 21 United States Code, Section 333(b)(1)(A) and Title 18 United States Code, Section 2.



CHUCK ROSENBERG

UNITED STATES ATTORNEY

Samuel J. Louis

Assistant United States Attorney